IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

DONALD A. COVERT,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**1:08CV447**
	)	
STRYKER CORPORATION and HOWMEDICA OSTEONICS CORPORATION,	)	
	)	
Defendants.	)	

ORDER AND RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE

This matter comes before the Court on the motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) filed by Defendant Howmedica Osteonics Corporation ("HOC" or "Defendant"). (Docket No. 8.) Plaintiff Donald A. Covert ("Plaintiff") has opposed the motion (Docket No. 13), and Defendant has filed a reply brief (Docket No. 16). For the reasons stated herein, the Court concludes that Defendant's motion should be granted.[1]

I. FACTUAL AND PROCEDURAL BACKGROUND

The Trident Ceramic Acetabular System (the "Trident Ceramic System") is an artificial hip replacement device that is indicated for patients requiring primary total hip

[1] Also pending before the Court are various motions filed by both sides for leave to file certain supplemental authorities, as well as certain corresponding motions to strike. (*See generally* Docket Nos. 19, 24, 30, 32, and 39.) Having carefully considered these motions, as well as the underlying authorities, the Court **GRANTS** the motions to supplement (Docket Nos. 24, 30 and 39) and **DENIES** the motions to strike (Docket Nos. 19 and 32).

replacement. (Docket No. 4, Complaint ("Compl.") ¶¶ 4, 13, 14.) It consists of four basic components, including a ball and socket which is made of alumina ceramic. (*Id*. ¶¶ 14, 15.) On February 3, 2003, HOC received Premarket Approval ("PMA") for the Trident Ceramic System, a "Class III" device, from the Food and Drug Administration (the "FDA").[2] (Docket No. 9, Def.'s Mem. in Support of Mot. to Dismiss, Ex. B, PMA Letter at 1.)

On June 2, 2005, Plaintiff Covert had a Trident Ceramic System implanted at Alamance County Hospital in Burlington, North Carolina. (Compl. ¶¶ 5, 18.) Following the surgery, Plaintiff detected "an audible sound emanating from the location" of the implant. (*Id*. ¶ 21.) As a result of the sound, Plaintiff experienced irritation, pain and discomfort. (*Id*. ¶ 22.) Plaintiff eventually had a "revision hip surgery" to remove the Trident Ceramic System and to insert a new hip replacement. (*Id*. ¶ 23.)

On or around May 22, 2008, Plaintiff filed this suit in the North Carolina Superior Court for Alamance County. (*Id*. at 36.) Plaintiff alleges eight counts, including: (1) failure to warn; (2) defective manufacturing; (3) defective design; (4) negligence and recklessness; (5) breach of express and implied warranties; (6) breach of implied warranty of fitness; (7) breach of implied warranty of merchantability; and (8) violations of North Carolina's Unfair and Deceptive Trade Practices Act (the "NCUDTPA"). (*Id* ¶¶ 65-138.) Additionally, while

[2] "[T]he Court may take judicial notice of and consider the public records of the FDA . . . without transforming this motion [to dismiss] into a motion for summary judgment." *Horne v. Novartis Pharms. Corp.*, 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008).

the Complaint does not contain a specific cause of action for fraud-on-the-FDA, Plaintiff's briefing makes clear that he also alleges Defendant misrepresented and/or withheld facts from that agency. (Docket No. 13, Pl.'s Br. in Opp'n ("Pl.'s Br.") at 3.)

On July 1, 2008, HOC and Stryker Corporation removed the matter to this Court on the grounds of diversity jurisdiction. (Docket No. 1, Notice of Removal at 1-2.) On August 12, 2008, Plaintiff took a voluntary dismissal, pursuant to Fed. R. Civ. P. 41, as to Stryker Corporation. (Docket No. 17.) On July 9, 2008, HOC filed the motion to dismiss that is presently before the Court. (Docket No. 8.)

II. DISCUSSION

Defendant HOC seeks dismissal of Plaintiff's complaint on the grounds that most or all of Plaintiff's claims are pre-empted by federal law and/or otherwise fail to state a claim upon which relief can be granted. Plaintiff opposes the motion on the merits. Both parties have filed briefs and other documents in support of their respective positions.

A. Express Federal Pre-emption

Article VI, Clause 2 of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." *Altria Group, Inc. v. Good*, 555 U.S. __, __, 129 S. Ct. 538, 543 (2008). Consistent with that command, courts have long recognized that state laws that conflict with federal law are "without effect." *Id*. (citing *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

When courts inquire "into the scope of a statute's pre-emptive effect," their analysis should be guided by the rule that "'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case." *Id*. (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). "Congress may indicate pre-emptive intent through a statute's express language or through its structure and purpose." *Id*. (citing *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). "If a federal law contains an express pre-emption clause, it does not immediately end the inquiry because the question of the substance and scope of Congress' displacement of state law still remains." *Id*. "Pre-emptive intent may also be inferred if the scope of the statute indicates that Congress intended federal law to occupy the legislative field, or if there is an actual conflict between state and federal law." *Id*. (citations omitted).

When addressing questions of pre-emption, courts must begin their analysis "with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id*. (citing *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947)). "That assumption applies . . . when Congress has legislated in a field traditionally occupied by the States." *Id*. (citations omitted); *but cf. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001) (Presumption does not arise where area of law being regulated is "inherently federal in character."). "Thus, when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'" *Good*, 129 S. Ct. at 543 (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

B. The Medical Device Amendments

The Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 301, *et seq*., has long required FDA approval for the introduction of new drugs to the market; however, until relatively recently, regulating the introduction of new medical devices was an issue left largely to the States to supervise as they deemed appropriate. *See, e.g., Riegel v. Medtronic, Inc.*, 552 U.S. __, __, 128 S. Ct. 999, 1002-03 (2008). In the 1960's and 1970's, the regulatory landscape underwent substantial changes, and certain states began adopting heightened safeguards, including provisions for premarket approval of medical devices. *Id*. at 1003. This, in turn, prompted Congress to pass the Medical Device Amendments of 1976 (the "MDA") (part of the FDCA), 21 U.S.C. § 360c, *et seq*., "which swept back some state obligations and imposed a regime of detailed federal oversight." *Id*.

The regulatory scheme created by Congress establishes various levels of oversight for medical devices depending on the risks that they present. *Id*. Class III devices, such as the Trident Ceramic System, receive "the most federal oversight." *Id*. The MDA establishes a "rigorous regime of premarket approval for new Class III devices." *Id*. at 1004 (comparing the rigorous PMA process to the less stringent test for "substantial equivalence," which is used to bring products to market which are sufficiently similar to pre-existing products which predated the MDA and which had been grandfathered into its new regulatory regime). The PMA process includes a review of the device's proposed labeling, as well as a thorough evaluation of its safety and effectiveness. *Id*.

Congress also chose to include an express pre-emption clause in the MDA, which states in relevant part that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Id. at 1003 (citing 21 U.S.C. § 360k(a)).

In *Riegel*, the Supreme Court considered the pre-emptive effect of this language and adopted a test for determining whether a state-law claim is expressly pre-empted by the MDA. *Id*. at 1006. *Riegel* stated that reviewing courts must first "determine whether the Federal Government [i.e., Congress or the FDA] has established requirements applicable to [the device]." *Id*. If such requirements exist, then the court must determine whether the state-law claims are based upon "requirements with respect to the device that are 'different from, or in addition to' the federal ones," and whether those state-law requirements relate to "safety and effectiveness," or any other matter included in a requirement applicable to the device under the FDCA.[3] *Id*. at 1006-07; *see also* 21 U.S.C. § 360k(a).

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[3] *Riegel* spent little time discussing the full breath of § 360k(a)(2), including its "relates to" language, which, as discussed below is quite broad, and its command that state-law claims "relat[ing] to . . . any other matter included in a requirement applicable to the device" under the FDCA would also be preempted. This is because the Court determined that "[s]afety and effectiveness are the very subjects" of Riegel's claims, and easily resolved the case on that basis. *Id*. at 1007.

The *Riegel* Court determined that the PMA process imposes "requirements" under the MDA because it is "specific to individual devices."[4] *Id*. at 1007. The Court then moved on to address the "critical issue" of whether Riegel's state common-law claims constituted "requirements," as that term is used in the MDA. *Id*. Relying upon *Bates*, 544 U.S. 431 (state-law "requirements" include both positive enactments as well as common-law duties) and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (same), *Riegel* determined that "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties." *Id*. at 1007-08. Indeed, the Court found that Riegel's suggestion that it draw a distinction between a State's common-law duties and its statutes and/or regulations to not be "required or even suggested by the broad language" of the MDA. *Id*. at 1008 ("[W]e will not turn somersaults" to create such a "perverse" distinction.).

In so doing, the majority rejected Justice Ginsburg's attempt in dissent to "narrow the pre-emptive scope of the term 'requirement' on the grounds that it is 'difficult to believe that Congress would, without comment, remove [virtually] all means of judicial recourse' for consumers injured by FDA-approved devices." *Id*. at 1008-09. Indeed, the majority stated that "by its terms," that is exactly what the MDA's pre-emption clause does.[5] *Id*. at 1009.

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[4] As discussed *infra*, state-law "requirements" need not be specific to the device in question, whereas a federal "requirement" apparently must. *Id*. at 1010 ("Nothing in the statutory text suggests that the pre-empted state requirement must apply *only* to the relevant device . . . .").

[5] The Court found Congress' intent to be so clear from the language that it used in the MDA pre-emption clause that it was "unnecessary to rely upon" the FDA's view of the statute. *Id*. at 1009 ("[W]e think the statute itself speaks clearly" to the meaning of the term "requirement.").

Accordingly, *Riegel* held that state common-law duties are "requirements," which in turn meant that state common-law claims based upon those duties are pre-empted by the MDA, at least to the extent that they seek to impose "different" or "additional" terms on the product in question than does federal law; however, the Court did not state that all state-law requirements are preempted. *Id*. at 1010-11 (discussing general requirements which regulate medical devices only incidentally and "parallel" claims).

1. State-Law Requirements Which Regulate Medical Devices Incidentally

In responding to Riegel's argument that state common-law claims are not pre-empted because they do not directly regulate the device in question, even if they may impose general "requirements," the Court was forced to examine the difference between state-law requirements that regulate directly, and those that regulate only indirectly. *Id*. at 1009-11. Ultimately, the Court found that "[n]othing in the statutory text suggests that the pre-empted state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general." *Id*. at 1010. However, before so deciding, the Court considered Riegel's arguments to the contrary, the *amicus curiae* brief of the FDA and certain specified FDA regulations.

Riegel's argument that the MDA only pre-empted state-law requirements which directly regulated the device in question "rest[ed] on the text" of 21 C.F.R. § 808.1(d)(1), "an FDA regulation which states that the MDA's pre-emption clause does not extend to certain duties, including '[s]tate or local requirements of general applicability where the purpose of

the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." *Id*. at 1010. The Court assumed, *arguendo*, that "this regulation could play a role in defining the MDA's pre-emptive scope," yet nonetheless found that it could not save Riegel's claims from pre-emption. *Id*. *Inter alia*, one reason the Court gave for rejecting Riegel's claim was that, in the FDA's view, the regulation did not extend to "general tort duties of care." *Id*.

Having already found the support that it needed in both the plain text of the actual pre-emption statute and in the FDA's *amicus curiae* brief, the Court went on to criticize the purported "reasoning" underlying 21 C.F.R. § 808.1(d)(1). In its *amicus* brief, the FDA attempted to draw a distinction between tort duties of care, which it maintained should be pre-empted, and other general state-law requirements, which it maintained should be "exclude[d] from pre-emption" on the grounds that they "relate only incidentally to medical devices." *Id*. The Court found this distinction "*less than compelling*, since the same could be said of general requirements imposed by electrical codes, the Uniform Commercial Code, or unfair-trade-practice law, which the regulation specifically excludes from pre-emption." *Id*. (emphasis added).

In the end, the Court determined that claims based on general tort duties of care should be pre-empted based not only on the clear language of the statute, but also on another regulation, 21 C.F.R. § 808.1(b), which "states that the MDA sets forth a 'general rule' pre-

empting state duties 'having the force and effect of law (whether established by statute, ordinance, regulation, *or court decision*)." *Id*. Indeed, the Court resolved that § 808.1(d)(1) "add[ed] nothing . . . but confusion" to the analysis; however, it did not explicitly strike the regulation down. *Id*. at 1011 ("Neither accepting nor rejecting the proposition that [§ 808.1(d)(1)] c[ould] properly be consulted to determine the [pre-emption] statute's meaning," the *Riegel* Court found that the regulation "fail[ed] to alter [its] interpretation" of the pre-emption statute in that instance.).

Post-*Riegel,* the great majority of courts addressing state-law requirements which regulate medical devices only incidentally have found that *Riegel* requires pre-emption. *See, e.g., In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009) ("In the [] months following *Riegel*, courts across the country have applied Section 360k(a) broadly, preempting all manner of claims . . . .") (finding breach of express and implied warranty claims, fraud claims and claims for deceptive trade practices pre-empted); *see also Heisner v. Genzyme Corp.,* No. 08-C-593, 2009 WL 1210633 (N.D. Ill. Apr. 30, 2009) (breach of express warranty claim pre-empted); *Horowitz v. Stryker Corp.*, No. CV-07-1572(DGT), 2009 WL 436406 (E.D.N.Y. Feb. 20, 2009) (breach of express warranty, implied warranty of fitness and implied warranty of merchantability claims, as well as state-law claim for deceptive trade practices pre-empted); *Parker v. Stryker Corp*., 584 F. Supp. 2d 1298 (D. Colo. 2008) (breach of express warranty, implied warranty of fitness and implied warranty of merchantability claims pre-empted); *Adkins v. Cytyc Corp*., No.

4:07CV00053, 2008 WL 2680474 (W.D. Va. July 3, 2008) (express and implied warranty claims pre-empted); *but cf. Hofts v. Howmedica Osteonics Corp*., 597 F. Supp. 2d 830 (S.D. Ind. 2009) (no pre-emption found, despite *Riegel's* overt criticism of § 808.1(d)(1)).

The Court believes that the position taken by these courts is bolstered by the central holding of *Riegel* itself. *See* 128 S. Ct. at 1006, 1011 (affirming dismissal of strict liability, negligence and breach of implied warranty claims on express pre-emption grounds). Indeed, despite the fact that *Riegel* declined to explicitly strike down 21 C.F.R. § 808.1(d)(1) *in toto*, it is apparent that the Court did, at the very least, significantly limit the effect of that regulation. *See id.* at 1011 (Rejecting the idea that "§ 808.1(d)(1) . . . [c]ould allow a claim . . . to escape pre-emption so long as such a claim could also be brought against objects other than medical devices."); *see also Horowitz*, 2009 WL 436406, at *13 n. 6 (Discussing *Riegel's* treatment of § 808.1(d)(1) and resolving that the Supreme Court found the regulation inapplicable because it "would effectively swallow the preemption rule."). In point of fact, *Riegel* affirmed the lower court's finding that an implied breach of warranty claim, which was ostensibly based on a state-law requirement of general import, was pre-empted. 128 S. Ct. at 1006, 1011.[6]

While the Supreme Court has not definitively articulated the effect of § 808.1(d)(1) since limiting it in *Riegel*, it would seem that the Court's most recent elucidation on the pre-

[6] This fact was somehow discounted by the *Hofts* court, which relied on § 808.1(d)(1) to justify denying dismissal of a breach of implied warranty claims. 597 F. Supp. 2d at 839-40.

emptive effect of the MDA further erodes that regulation's potential applicability. Indeed, since *Riegel*, the Supreme Court has had at least one occasion to reflect on the MDA's pre-emption clause and its scope, which is, to say the least, broad.

In *Altria Group, Inc. v. Good*, discussed *supra*, the Court examined whether claims brought under the Maine Unfair Trade Practices Act (the "MUTPA") were pre-empted by the Federal Cigarette Labeling and Advertising Act (the "FCLAA"). 129 S. Ct. 538. The Court ultimately concluded that the MUTPA represented a state-law "requirement," *see id*. at 545 (the FCLAA pre-empts "common-law rules as well as positive enactments"), however, it determined that said "requirement" was not pre-empted because it was based on a general duty not to deceive, and not "based on smoking and health." *Id*. at 547.

In resolving that said claims were not pre-empted by the FCLAA, the Court was called upon to distinguish that Act's pre-emption statute from the pre-emption statutes found in the MDA and the Airline Deregulation Act (the "ADA"), respectively. *Id*. at 547-49. In so doing, the Court held that the language of both the MDA and the ADA was "much broader" than that of the FCLAA. *Id*. at 548. Indeed, the Court found that the "relating to" language Congress used in the MDA and the ADA was significantly more encompassing than the operative language of the FCLAA pre-emption statute, which pre-empted only state-law claims "based on smoking and health." *Id*. at 549.

Writing for the Court, Justice Stevens stated that the phrase "relating to" is "*unquestionably*" broader than the phrase "based on," because the former is "synonymous

with 'having a connection with,'" whereas the latter "describes a more direct relationship." *Id*. at 548 (emphasis added). The Court stated that pre-emption statutes (like the MDA), which use "relating to" language have "unusual breadth [and scope]." *Id*. (discussing *Am. Airlines, Inc. v. Wolens*, 513 U.S. 219 (1995)). The Court went on to liken the scope of the ADA's pre-emption clause (and by proxy the MDA's pre-emption clause, which uses the same language) to the scope of the pre-emption clause found in the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1144(a) ("ERISA"), and stated that where Congress utilizes the phrase "relating to," it is indicating its "intent to pre-empt a large area of state law." *Id*. (citing *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383-84 (1992)).

Having distinguished the FCLAA's pre-emption clause from that of the ADA and MDA, the Court stated that the "based on smoking and health" language of the FCLAA, did not encompass the plaintiff's MUTPA claims, which it had previously found to be a "requirement." *Id*. at 549. Implicit in this finding is the fact that the "unusual breath" of both the ADA and/or MDA would likely encompass those same MUTPA claims. *Accord Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 8 (1987) (the words "relate to" should be "construed expansively: '[a] law relates to [a federal requirement], in the normal sense of the phrase, if it has a connection with or reference to such [federal requirement].'") (quoting *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96-97 (1983)).

In any event, based on the above authorities, this Court joins *Horowitz* and *Parker* (both of which dealt with the Trident Ceramic System) in finding that state-law requirements of general import, which regulate a medical device only incidentally, are subject to federal pre-emption in the same way as those state-law requirements which specifically target the device in question. *Accord Riegel*, 128 S. Ct. at 1010 ("Nothing in the statutory text [of § 360k(a)] suggests that the pre-empted state requirements must apply *only* to the relevant device, or only to medical devices and not to all other products and all actions in general.").

To be clear, this Court considers the fact that a state-law "requirement" (i.e., any common-law duty or positive enactment) may regulate a medical device only incidentally to be too slight a distinction to merit excluding that requirement from pre-emption under the MDA, especially given the "unusual breath" of the language Congress used in drafting the MDA, which is to be interpreted "expansively." Accordingly, all of Plaintiff's state-law claims are subject to pre-emption to the extent they "relate to" (i.e., "have a connection with" or "reference to") the labeling, safety or effectiveness of the Trident Ceramic System, as those issues were the subject of the FDA's PMA process, provided, of course, that those state-law claims are not "parallel," as discussed below.

2. "Parallel" Claims

In *Riegel*, the Court noted an exception to express pre-emption under § 360k(a) for "parallel" claims. 128 S. Ct. at 1011. This is because "State requirements are [expressly] pre-empted under the MDA only to the extent that they are 'different from, or in addition to'

the requirements imposed by federal law." *Id*. (citing 21 U.S.C. § 360k(a)). The Court stated that the MDA "does not [expressly] prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations," because in such an instance, the state law duties would "parallel" rather than "add to" the relevant federal requirements. *Id*. (citing *Lohr*, 518 U.S. at 495, 513). Put another way, *Riegel* supports the proposition that where a claim asserts that a medical device "violated state [] law notwithstanding compliance with the relevant federal requirements," that claim is not "parallel," and therefore may be subject to express pre-emption under § 360k(a). *Riegel*, 128 S. Ct. at 1011 (discussing the district court's rationale for finding pre-emption under the MDA).[7]

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[7] The Court notes that *Riegel* did not provide an exhaustive discussion of "parallel" claims under the MDA because the plaintiff in that case failed to adequately preserve the issue on appeal. 128 S. Ct. at 1011. Notwithstanding this fact, the Court believes that the above-cited passages represent an accurate, if not technically binding, statement of the law on this issue. In point of fact, the Supreme Court recently examined the issue of "parallel requirements," albeit in the context of a different, yet similarly constructed statute, and reached largely consistent results. *See, e.g., Bates*, 544 U.S. 431. In *Bates*, the Court addressed the pre-emptive power of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), which contains an express pre-emption clause, 7 U.S.C. § 136v(b), not unlike that of the MDA. *See* 544 U.S. at 447-48 (FIFRA pre-empts certain state-law "requirements" that are "in addition to or different from" the relevant federal ones). *Id*. at 447. Specifically, the Court found that a state-law action which "seeks to enforce a federal requirement does not impose a requirement that is different from or in addition to, requirements under federal law." *Id*. at 448 (citations omitted). Further, *Bates* stated that "[i]n undertaking a pre-emption analysis at the pleadings stage of a case, a court should bear in mind the concept of equivalence." *Id*. at 454. In order to "survive pre-emption," the Court stated, a state-law requirement need be "genuinely equivalent" to the relevant federal requirement. *Id*. Moreover, since the Supreme Court's decision in *Bates*, at least one circuit court has applied this requirement of "genuine" equivalency to the MDA's pre-emption clause. *See, e.g., McMullen v. Medtronic, Inc.*, 421 F.3d 482, 488-89 (7th Cir. 2005) ("[T]he plaintiff must show that the requirements are "*genuinely* equivalent.") ("State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law."). In any event, the Court believes *Riegel* controls this situation and will apply it in resolving the present controversy.

However, while *Riegel* confirmed that, in accordance with § 360k(a), "*certain* state-law causes of action[]" can be brought which "parallel federal *safety* requirements," it is not the case that just "any violation of the FDCA [including the MDA] will support a [parallel] state-law claim." *See, e.g., Buckman*, 531 U.S. at 353 (pre-empting state-law tort claims which alleged that a plaintiff was injured by a manufacturer's fraud on the FDA) (emphasis added). Indeed, where a plaintiff's claims sound in fraud, and "exist solely by virtue of the FDCA disclosure requirements," those claims may not properly lie. *Id*. at 347-48, 352-53 (Where a manufacturer's "dealings with the FDA were prompted by the MDA, and the very subject matter of [that manufacturer's] statements were dictated by [its] provisions," a consumer may not sue that manufacturer for those misrepresentations or omissions, either under the MDA or state law, because the FDA is "amply" empowered to "punish and deter fraud" and because to allow such suits could "skew" the "delicate balance of statutory objectives" the FDA is charged with carrying out.).

The Supreme Court's decision to completely pre-empt fraud-based claims on the one hand, while still giving plaintiffs the option to bring "certain" state-law claims which "parallel federal safety [and labeling] requirements" on the other, highlights the difference between the principles of express and implied pre-emption. *Cf. Geier v. Am. Honda Motor Co*., 529 U.S. 861, 869 (2000) (An express "pre-emption provision, by itself, does not foreclose (through negative implication) 'any possibility of implied [conflict] pre-emption'")

(citing *Freightliner Corp. v. Myrick*, 514 U.S. 208, 288 (1995) (discussing *Cipollone*, 505 U.S. at 517-18)).

Riegel relied on a different analytical framework to determine whether federal pre-emption was appropriate than did *Buckman*. Indeed, the analysis of the former is rooted in principles of express pre-emption, *see Riegel*, 128 S. Ct. at 1003 (looking to § 360k(a)(1) to determine that "parallel" state claims may survive pre-emption), whereas the latter looked to the "inherently federal" nature of the "relationship between a federal agency and the entity it regulates" to determine that fraud-based state-law claims should be impliedly pre-empted, *see Buckman*, 531 U.S. at 347-48, 352 (fraud-on-the-FDA claims "impliedly" pre-empted) (no presumption against pre-emption arose as this is not a traditional area of state regulation).

Accordingly, the Court finds that certain of Plaintiff's claims "relating to" the labeling, safety and/or effectiveness of the Trident Ceramic System may escape pre-emption under 21 U.S.C. § 360k(a), so long as they are premised solely upon HOC's non-compliance with an applicable federal "requirement," whereas such claims that are premised on anything other than said non-compliance are expressly pre-empted. Moreover, the Court finds that any claims which are based upon an alleged breach of an FDA disclosure requirement, while not necessarily expressly pre-empted, are impliedly pre-empted by federal law.

With this framework in mind, the Court must consider whether Plaintiff has sufficiently pled any claims which survive both express pre-emption under § 360k(a) and implied pre-emption under *Buckman*, and which state a cause of action upon which relief can

be granted. *Accord Stevens v. Pacesetter, Inc.*, No. 3:07-cv-3812, 2008 WL 2637417, at *1 (D.S.C. Apr. 1, 2008) (only a "narrow category" of claims survive *Riegel*); *cf. In re Medtronic*, 592 F. Supp. 2d at 1161 (In light of *Buckman* and *Riegel*, "nearly all types of claims concerning FDA-approved medical devices are preempted."). The Court concludes that under the complaint in this action, Plaintiff has not adequately pled any such claim.

C. Motion to Dismiss Pursuant to Rule 12(b)(6)

A Rule 12(b)(6) motion tests the legal sufficiency of the complaint. *See, e.g., Randall v. United States*, 30 F.3d 518, 522 (4th Cir. 1994). To survive such a motion, "the facts alleged 'must be enough to raise a right to relief above the speculative level' and must provide 'enough facts to state a claim to relief that is plausible on its face.'" *Robinson v. Am. Honda Motor Co.*, 551 F.3d 218, 222 (4th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)). Courts must "construe factual allegations in the non-moving party's favor and will treat them as true, but the court is not bound by the complaint's legal conclusions." *Id*. (citations omitted).

Here, Plaintiff has offered five reasons why HOC's motion to dismiss should be denied, namely that: (1) the motion is premature; (2) HOC has failed to prove that pre-emption applies; (3) a pre-emption defense cannot be founded upon fraud; (4) Plaintiff's tort claims are "parallel" claims; and (5) Plaintiff's remaining claims are outside the purview of pre-emption (Pl.'s Br. at 5-17). For the reasons stated herein, the Court finds Plaintiff's arguments unpersuasive.

1. The Timing of HOC's Motion to Dismiss

Without citing any pertinent authority, Plaintiff argues that "[d]ismissal based on alleged preemption is inappropriate without an examination of the complete factual record." (*Id*. at 7.) He states that his complaint is "replete with allegations" of HOC's violations of "pivotal federal regulations," which ostensibly relate to the alleged "parallel" nature of certain claims. (*Id*. at 6.) Indeed, he states that dismissing his case "without first allowing [it] to proceed through discovery in order to determine if there is in fact sufficient evidence" to support his claim that "Defendant has violated [federal law] is unjust at best." (*Id*. at 7.)

This argument seems to be premised on the fact that *Riegel* and a few other MDA pre-emption cases were decided on motions for summary judgment, rather than motions to dismiss. (*See id*. ("Most, if not all" MDA pre-emption cases are decided on summary judgment.) (citing *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999); *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776 (E.D. La. 2007); *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886 (D. Minn. 2006); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, No. 05-1708 (DWF/AJB), 2007 WL 844683 (D. Minn. Mar. 19, 2007)).)

However, the Court notes that Plaintiff has failed to cite any authority which would indicate that it should apply any standard other than the normal "motion to dismiss" standard in resolving the present motion. Plaintiff has failed to show that a motion to dismiss based on MDA pre-emption should be treated any differently than any other motion to dismiss

under Rule 12(b)(6). As such, the Court must look to well-established precedent to determine if Plaintiff's claim of entitlement to discovery has merit.[8]

In *Bell Atlantic Corp. v. Twombly*, the Supreme Court examined "the practical significance" of what it called "the Rule 8 entitlement requirement." 550 U.S. 544, 557 (2007) (discussing Fed. R. Civ. P. 8). The Court stated that "when the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court." *Id*. at 558 (internal quotation marks, punctuation and citations omitted); *see also Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 346 (2005); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 995 (N.D. Ill. 2003) (Posner, J., sitting by designation) ("[S]ome threshold of plausibility must be crossed . . . before a . . . case should be permitted to go into its inevitably costly and protracted discovery phase.") (cited favorably in *Twombly*, 550 U.S. at 558).

Indeed, the *Twombly* Court explained that "something beyond the mere possibility of [a federal violation] must be alleged, lest a plaintiff with a largely groundless claim be allowed to take up the time of a number of other people, with the right to do so representing

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[8] Post-*Riegel*, more than a few courts have decided MDA pre-emption issues at the pleadings stage, rather than on summary judgment. *Accord In re Medtronic*, 592 F. Supp. 2d 1147 (granting motion to dismiss); *Heisner*, 2009 WL 1210633 (same); *Horowitz*, 2009 WL 436406 (same); *Bausch v. Stryker Corp.*, No. 08 C 4248, 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008) (same); *Parker*, 584 F. Supp. 2d 1298 (same); *Adkins*, 2008 WL 2680474 (same); *Stevens*, 2008 WL 2637417 (same); *cf. Lohr*, 518 U.S. at 495 ("[T]he pre-emption issue was decided on the basis of the pleadings.").

an *in terrorem* increment of the settlement value." 550 U.S. at 557-58 (citing *Dura*, 544 U.S. at 347) (internal quotation marks and punctuation omitted). In that vein, the Court stated that "a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed [to discovery]." *Id*.

"[I]t is only by taking care to require allegations that reach the [requisite] level [of specificity]," the Court reasoned, "that we can hope to avoid the potentially enormous expense of discovery in cases with no reasonably founded hope that the discovery process will reveal relevant evidence to support [the alleged] claim." *Id*. at 559 (citing *Dura*, 554 U.S. at 347) (internal quotation marks and brackets omitted). Gone are the days when a plaintiff could assert "a wholly conclusory statement of claim" and survive a motion to dismiss simply because his "pleadings left open the possibility that [he] might later establish some set of undisclosed facts to support recovery." *Id*. at 561-62 (abrogating the "no set of facts" standard set forth in *Conley v. Gibson*, 355 U.S. 41 (1957)) ("[A]fter puzzling the profession for 50 years, this famous observation has earned its retirement.") (internal quotation marks and punctuation omitted).

As the *Twombly* Court implied, "Mr. Micawber's optimism" is not enough to allow a plaintiff to survive a motion to dismiss and proceed on to discovery. *Id*. at 562. Thus, the Court concludes that Plaintiff's entitlement to discovery, or lack thereof, will turn on whether he has sufficiently pled an entitlement to relief under Rule 8 generally, and in particular whether his pleadings have established a "reasonably founded hope" that discovery "will

reveal relevant evidence" to support that claim. *Accord Ashcroft v. Iqbal*, __ U.S. __, 129 S. Ct. 1937, 1953-54 (2009) (*Twombly*, which applies to "*all civil actions*," dictates that where a plaintiff's "complaint is deficient under Rule 8, he is not entitled to discovery, cabined or otherwise.") (emphasis added).

2. The Burden to "Prove" Pre-emption

Next, Plaintiff argues that Defendant has failed to establish pre-emption under the circumstances of this case, and that a "strong presumption" against pre-emption saves his claims from dismissal. (Pl.'s Br. at 8.) Relying on *Bravman v. Baxter Healthcare Corp*., Plaintiff argues that HOC "bears the burden of proof and must establish that Congress has clearly and unmistakably manifested its intent to supersede state law." (*Id*. (citing 842 F. Supp. 747, 753 (S.D.N.Y 1994)).

As discussed *supra*, it is apparent that Congress did "clearly and unmistakably" manifest an intent to supersede a large area of state law, including, but not necessarily limited to, any common law duty or positive enactment which "relates to" the labeling, safety and/or effectiveness of the Trident Ceramic System. Indeed, the only recognized exception to express MDA pre-emption that this Court is aware of relates to "parallel" claims; however, as discussed below, Plaintiff's complaint does not sufficiently plead any "parallel" claims. Moreover, even if certain of Plaintiff's claims were not expressly pre-empted, Plaintiff would have the additional hurdle of the doctrine of implied pre-emption, which would act to bar any claims based on an alleged violation of a disclosure duty established under the MDA. In any

event, assuming, *arguendo*, that Plaintiff is correct in asserting that HOC bears the burden of establishing pre-emption, the Court finds that HOC has adequately carried that burden.

3. Fraud and Pre-emption

Plaintiff's third argument against dismissal is that HOC should not receive the benefit of a federal pre-emption defense because Plaintiff has alleged that HOC engaged in certain "fraudulent violation[s] of key regulations of the [FDA]." (Pl.'s Br. at 10.) However, Plaintiff does not cite a single authority to support his position. His postulate appears to be that: (1) HOC has cited a number of cases which counsel in favor of finding federal pre-emption; (2) none of the plaintiffs in those cases alleged that the defendant committed a fraud on the overseeing agency; and (3) here, Plaintiff has alleged such a fraud. Thus, he reasons that pre-emption cannot be applied in this case. In addition to being wholly conclusory and unsupported, the argument evidences a misunderstanding of *Buckman* and federal pre-emption generally. *Accord In re Medtronic*, 592 F. Supp. 2d 1147 (pre-empting a host of claims, despite alleged fraud and/or deceptive acts); *cf. Horowitz*, 2009 WL 436406 (same).

As stated above, *Buckman* makes clear that state-law claims based on a manufacturer's alleged breach of federal disclosure rules are impliedly pre-empted due to the "inherently federal character" of the relationship between the FDA and said manufacturer. 531 U.S. at 347-48 ("Policing fraud against federal agencies is hardly a 'field which the States have traditionally occupied.'") (citation omitted). Indeed, Congress adopted a "federal statutory scheme" that "amply empowers the FDA to punish and deter fraud" and this

authority is used to achieve a "delicate balance" of statutory objectives, which can be "skewed" by allowing "fraud-on-the-FDA" claims under state law. *Id*. at 348-49 (The FDA has "a variety of enforcement options . . . to make a measured response to suspected fraud.").

It is this statutory scheme that gives the FDA the "flexibility" to "pursue[] difficult (and often competing) objectives" "without intruding upon decisions statutorily committed to the discretion of health care professionals." *Id*. at 349-50. Further, the Supreme Court clearly stated some years ago that, in addition to being unduly burdensome on manufacturers and the FDA itself, allowing "State-law fraud-on-the-FDA claims" would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id*. at 350-51. Thus, the Court reasoned, because of the "extraneous pull" this "sort of litigation" would have on the scheme established by Congress, cases sounding in fraud-on-the-FDA are impliedly pre-empted. *Id*. at 353. Plaintiff has failed to distinguish *Buckman* in any meaningful way, or to cite to any other authority which would indicate that the Court should not apply ordinary principles of federal pre-emption due to the simple fact that Plaintiff has alleged a fraud upon a federal agency.

4. The "Parallel" Nature of Plaintiff's Claims

In opposing HOC's motion to dismiss, Plaintiff also argues that his "tort" claims are "parallel" to the applicable federal requirements, and thus not pre-empted. (Pl.'s Br. at 12-16.) Indeed, Plaintiff states that HOC's failure to meet certain specific federal requirements, which were applicable to the Trident Ceramic System, as well as HOC's statements and

omissions to the FDA, "directly and proximately" caused said system to be in violation of federal law, and proximately caused harm and injury to him. (*Id*. at 15.)

In support of this position, Plaintiff cites to, *inter alia*, two warning letters issued by the FDA to HOC, arising from inspections of its facilities in Ireland and New Jersey. (*Id*. at 13-15.) In particular, Plaintiff alleges that these inspections, which took place in 2006 and 2007 respectively, revealed violations of the FDA's Current Good Manufacturing Practices. (*Id*.) However, Plaintiff does not allege that the Trident Ceramic System, which was implanted in him in 2005, was manufactured in either facility, or that it was ever the subject of any FDA action or recall, or that it has ever been found by the FDA to be in violation of any particular regulation, or even that there is an independent reason to believe that *his particular system* violated a federal regulation in any way.

This Court is not the first to weigh in on the general facts presented in this case, or the legal questions they raise. Indeed, no less than four other federal courts have heard motions to dismiss litigation related to the Trident Ceramic System, and have evaluated virtually identical factual allegations as those levied by Plaintiff in the case at bar. *See, e.g., Horowitz*, 2009 WL 436406 (finding claims pre-empted); *Bausch*, 2008 WL 5157940 (same); *Parker*, 584 F. Supp. 2d 1298 (same); *but cf. Hofts*, 597 F. Supp. 2d 830 (claims not pre-empted based on pleadings). Accordingly, this Court is in the fortuitous position of being able to glean what lessons it can from the collective experiences of these courts, while at the same time, not being bound by any of their decisions. *See, e.g., Hanes Cos., Inc. v. Contractor's*

Source, Inc., No. 1:08CV334, 2008 WL 4533989, at *13 n.16 (M.D.N.C. Oct. 6, 2008) (citing *McCoy Lumber Indus., Inc. v. Niedermeyer-Martin Co.*, 356 F. Supp. 1221, 1225 (M.D.N.C. 1973)).

In *Horowitz*, U.S. District Judge Trager of the Eastern District of New York became one of the most recent jurists to be heard on the issue of what constitutes a "parallel" claim under the MDA. 2009 WL 436406, at *6-8. Relying in part on *Bausch* and *Parker*, both of which had considered virtually identical facts, he found that "in order to survive preemption under the MDA a plaintiff must demonstrate a cognizable link between the defendant's [alleged] federal violations and plaintiff's [alleged] injury." *Id.* at *7; *accord Parker*, 584 F. Supp. 2d at 1301-02 (plaintiff's complaint was deficient in that it failed to provide any factual detail substantiating her claim that the Trident system was defective as a direct result of defendants having manufactured it in violation of the PMA process); *cf. Bausch*, 2008 WL 5157940, at *4 (simply alleging that the defendants violated federal regulations did not necessarily mean that the plaintiff's claims were premised on those violations).

In finding the plaintiff's claims to be pre-empted, Judge Trager stated in *Horowitz* that a reviewing court should require factual "amplification as to how" a defendant's alleged federal violations relate to the putative plaintiff's claims. 2009 WL 436406, at *9 n.5 (discussing the Rule 8 pleading standard enunciated in *Twombly*). In so doing, the court considered and expressly rejected the analysis utilized in *Hofts*, which considered the same facts and came to an opposite conclusion.

In *Hofts*, the court reasoned that a plaintiff's allegations that a manufacturer failed to meet FDA requirements were sufficient, in and of themselves, to withstand pre-emption on a motion to dismiss. 597 F. Supp. 2d at 838 (It is an "unusually stringent application of *Twombly*" to require further specificity at the pleadings stage.). Indeed, the *Hofts* court reasoned that because claims relating to defective medical devices generally are not subject to the "particularity" pleading requirements of Rule 9, dismissal would be inappropriate. *Id*.

In this Court's view, *Twombly* requires more from a plaintiff pleading a case such as that attempted by Plaintiff Covert than the *Hofts* court would demand. Rather, the *Horowitz*, *Bausch,* and *Parker* courts are found to be more persuasive with regard to the pleading standards of *Twombly* (which were recently confirmed by the Supreme Court in *Iqbal*). *Twombly* abrogated the "no set of facts" standard set forth in *Conley* for construing Rule 8, and heralded a new standard for resolving motions to dismiss, which was based on the "plausibility" of a plaintiff's claims. 550 U.S. at 560-63. Now, a plaintiff must "nudge[] [his] claims across the line from conceivable to plausible," in order to stave off dismissal, which feat can only be accomplished by pleading "enough facts to state a claim to relief that is plausible *on its face*." *Id*. at 570 (emphasis added).

As a starting point for analysis, it is essential to note that Rule 8(a)(2) "requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is *and the grounds upon which it rests.*" *Id*. at 555 (citing *Conley*, 355 U.S. at 47) (emphasis added). "While a complaint

attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id*. (citations omitted). The complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the ASSUMPTION THAT ALL THE allegations in the complaint are true (even if doubtful in fact)." *Id*. (internal citations omitted). Indeed, the "pleading must contain something more . . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action." *Id*. (citation omitted).

Twombly made clear that Rule 8(a) "contemplate[s] [a] statement of circumstances, occurrences, and events in support of the claim presented and does not authorize a pleader's bare averment that he wants relief and is entitled to it." *Id*. at 556 n.3. Without this factual "showing" of entitlement to relief, it is difficult to see how a complaint would satisfy the requirement that it provide the defendant not only with "fair notice" of the nature of the claim, but also the "grounds" upon which it rests. *Id*.

This means that a complaint must contain "allegations plausibly suggesting," an entitlement to relief, not allegations which are "merely consistent with" that conclusion. *Id*. at 557. Put another way, the plaintiff's "plain statement" of his claim must "possess enough heft" to "show" that, if all he says is true, he is "entitled to relief." *Id*. Indeed, where a

complaint "stops short of the line between [the] possibility and [the] plausibility of entitlement to relief," it must be dismissed, absent "some further factual enhancement." *Id*.

To be clear, the mere fact that a complaint comes "close to stating a claim" is not enough. *Id*. Indeed, the plaintiff must cross two theoretical barriers before he "enter[s] the realm of plausible liability." *Id*. n.5. Most obviously, he must cross the "line between the conclusory and the factual." *Id*. (citing *DM Research, Inc. v. College of Am. Pathologist*s, 170 F.3d 53, 56 (1st Cir. 1999)). More importantly, however, he must also cross the line "between the factually neutral and the factually suggestive." *Id*. For this very reason, *Twombly* stated that "a district court must retain the power to insist upon some specificity in pleading" when deciding a motion to dismiss. *Id*. at 558 (citation omitted).[9]

As discussed above, in order to avoid express pre-emption, Plaintiff must allege a state-law claim which is "genuinely equivalent" to a federal requirement, i.e., one which is premised upon the violation of a federal "requirement." Further, in order to ultimately show an entitlement to relief under any of his "tort" theories of recovery, he must also show that said violation caused his injury. *See generally City of Thomasville v. Lease-Afex, Inc.*, 300 N.C. 651, 656, 268 S.E.2d 190, 194 (1980) ("As in any action for negligence, the essential elements of a suit for products liability sounding in tort must include . . . evidence of a

[9] In reaching this conclusion, the *Twombly* Court took care to state that it was "not apply[ing] any 'heightened' pleading standard," nor was it seeking "to broaden the scope" of Rule 9 of the Federal Rules of Civil Procedure. *Id.* at 569 n.14 (Rule 9 deals with a specified group of claims subject to a high risk of abusive litigation, which require a plaintiff to "state factual allegations with greater particularity" than normally required under Rule 8.).

standard of care owed . . . breach of that standard of care . . . injury caused . . . by the breach, and . . . loss because of the injury.").

Thus, in order to survive the present motion to dismiss, Plaintiff's complaint must put HOC on notice both of the nature of his claims (i.e., that they are "parallel" to federal requirements), as well as the grounds upon which he maintains he is ultimately entitled to relief (i.e., the factual basis for the allegations that his injuries were caused by HOC's violation of an identifiable federal requirement or requirements). Clearly, Plaintiff has adequately put HOC on notice, at least in argument, if not in pleadings, that he believes his claims are "parallel" in nature; however, he has failed to put HOC on notice of the grounds of his purported entitlement to relief in that it is not at all clear whether or how the alleged violations relate to his alleged injuries.

Plaintiff is correct in stating that his complaint is rife with allegations of wrongdoing by HOC in both the PMA process and in the subsequent manufacturing of their products; however, he has not alleged any particular non-conclusory link between that alleged wrongdoing and his particular injuries, let alone a causal one, as he would ultimately be required to do before he is entitled to recover anything from HOC. Thus, at this point, the Court is left with nothing more than a mere "suspicion" that Plaintiff may have a legally cognizable claim, which, as stated above is insufficient to survive a motion to dismiss.

While Plaintiff did not need to plead detailed or particularized facts to adequately state his claims, he nonetheless was obligated to allege enough facts, if taken as true, to show an

entitlement to relief that is plausible on its face. This Court, after reviewing Plaintiff's complaint, should not have to speculate about how it is that Plaintiff believes he is entitled to relief. To be clear, without such a showing, it would be impossible for the Court to have a "reasonably founded hope" that Plaintiff "would be able to make [his] case," if allowed to proceed to discovery.

The clearest statement of Plaintiff's "parallel" claims appears at paragraph 53 of the Complaint. There, Plaintiff alleges that:

> The Defective Device is unreasonably dangerous and defective because: a. the manufacturing process for the acetabular hip implant device and certain of their components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the acetabular hip implant device; b. the failure of the manufacturing process for the acetabular hip implant device and certain of their components to satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices resulted in unreasonably dangerous manufacturing defects; and c. the Defendant failed to warn of the unreasonable risks created by these manufacturing defects.

(Compl. ¶ 53.)

However, this allegation lacks any factual development and contributes nothing to the "plausibility" of Plaintiff's claims. Indeed, this paragraph is an example of why Plaintiff's complaint does not venture beyond mere speculation. *Accord Iqbal*, 129 S. Ct. at 1951 (finding "bare assertions" of this sort too conclusory to be entitled to a presumption of truth).

After thoroughly reviewing all of Plaintiff's complaint, the Court finds that his allegations hardly cross the line from conclusory to factual (if at all), let alone the line from factually neutral to factually suggestive of a right to relief. Indeed, it would seem that

Plaintiff has offered the Court little more than a formulaic recitation of the elements of a "parallel" claim, coupled with vague citations to generic allegations of wrongdoing by HOC, without any identifiable tie between the two. The mere allegation that HOC may have violated some federal "requirement" in one or more instances is not enough to "plausibly suggest" that it has violated any such federal "requirement" in this particular instance, let alone that such violation actually caused the harm that Plaintiff presently alleges.

The Court concludes that *Twombly* requires more than the generalized, anecdotal and conclusory allegations offered by Plaintiff's complaint. Indeed, as one district court aptly stated, Plaintiff "cannot simply incant the magic words '[HOC] violated FDA regulations' in order to avoid preemption." *See, e.g., In re Medtronic*, 592 F. Supp. 2d at 1158 (citing *Parker*, 584 F. Supp. 2d at 1301 (conclusory allegations of federal violations are insufficient to save claim from pre-emption)). Accordingly, the Court joins *Horowitz*, *Bausch* and *Parker* in finding that Plaintiff has failed to adequately plead his "tort" claims as "parallel" under the standard set forth in *Twombly*; accordingly, these claims are pre-empted and must be dismissed.[10]

[10] In order to "survive" MDA pre-emption under *Twombly*, a plaintiff must point to a specific federal requirement, show how it was violated, and in this case, show how said violation resulted in the injury complained of. *Cf. In re Medtronic*, 592 F. Supp. 2d at 1158-59 (discussing *Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790 (W.D. La. 2008)). For instance, where a plaintiff alleged that his injury resulted from a device being packed with the wrong size "guidewire," he adequately pled a "parallel' claim. *Id.* at 1159 (citing *Rollins*, 583 F. Supp. 2d at 800). However, where the complaint fails to cross this minimal threshold of specificity, dismissal is appropriate. *Id.*

5. The Scope of MDA Pre-emption

Plaintiff's final argument against dismissal is that his breach of express warranty claims and/or his NCUDTPA claims fall outside of the scope of the MDA's pre-emption clause. Although HOC appears to concede that in some instances, express breach of warranty claims may not be subject to MDA pre-emption, in this instance, as stated above, given the "unusual breath" of the "relating to" language used in § 360k(a), it would seem that these claims are subject to express pre-emption under that statute, just like his tort claims, *see, e.g., In re Medtronic*, 592 F. Supp. 2d 1147 (dismissing breach of express and implied warranty claims, fraud claims and claims for deceptive trade practices as pre-empted); *see also Heisner*, 2009 WL 1210633 (breach of express warranty claim pre-empted); *Horowitz*, 2009 WL 436406 (breach of express and implied warranty claims, as well as claim for deceptive trade practices pre-empted); *Parker*, 584 F. Supp. 2d 1298 (breach of express and implied warranty claims pre-empted); *Adkins*, 2008 WL 2680474 (breach of express and implied warranty claims pre-empted), and/or implied pre-emption under *Buckman*, to the extent they are based on an alleged violation of an FDA disclosure requirement.

Moreover, these particular claims would also be subject to dismissal on the grounds that they fail to state claims upon which relief can be given. Indeed, as HOC has adequately argued, Plaintiff has failed to sufficiently plead a claim for breach of express warranty under North Carolina law because his complaint fails to identify "[a]ny affirmation of fact or promise . . . made by [HOC] . . . which relates to the [Trident Ceramic System] and bec[ame]

part of the basis of the bargain" between Plaintiff and HOC. *See, e.g.*, N.C. Gen. Stat. § 25-2-313 (2008); *Pake v. Byrd*, 55 N.C. App. 551, 552 (1982).

Further, Plaintiff's NCUDTPA claims are similarly deficient. Here again, as HOC has persuasively argued, Plaintiff has failed to identify any specific representations, omissions or deceptive or misleading acts that affected commerce and caused Plaintiff injuries. *See, e.g., First Atl. Mgmt. Corp. v. Dunlea Realty Co*., 131 N.C. App. 242, 252 (1998); *accord Horowitz*, 2009 WL 436406 (dismissing plaintiff's breach of warranty and "deceptive acts or practices" claims on similar inadequate pleading grounds). Even if the Court were to assume, *arguendo*, that these claims were not pre-empted, they would nonetheless be dismissed for failing to state a claim upon which relief could be given.

Conclusion

For the foregoing reasons, **IT IS RECOMMENDED** that Defendant's motion to dismiss (Docket No. 8) be granted. Further, **IT IS ORDERED** that, consistent with the above, all pending motions to supplement the record (Docket Nos. 24, 30 and 39) be **GRANTED**, and all pending motions to strike (Docket Nos. 19 and 32) be **DENIED**.

/s/ P. Trevor Sharp
United States Magistrate Judge

Date: August 5, 2009